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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

792-21 RCE 2

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on May 29, 2007

Signature

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name

Marcy H. Mancuso

Application Number

09/556,671

Filed

April 24, 2000

First Named Inventor

Michael Stephen Austin

Art Unit

3733

Examiner

Reimers, Annette R.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐

applicant/inventor.

☐

assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)☒

attorney or agent of record.

Registration number 41,321☐

attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 _____

Signature

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Typed or printed name

973-331-1700

Telephone number

May 29, 2007

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒*Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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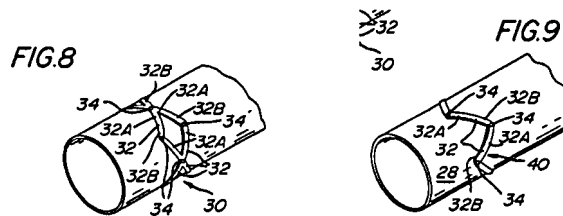
Section 102 Rejections

Claims 1-9, 13, 15, 17-24, 27, 29, 31, 33-37 and 42-45 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,122,154 to Rhodes (hereinafter "Rhodes"). Applicant respectfully traverses.

Rhodes describes an intraluminal graft having a plurality of stents. The stents do not include undulating wires, but rather are pivotally connected straight stent struts. Rhodes describes it stents, as follows:

[E]ach stent member 30 basically comprises a plurality of interconnected links or struts 32. Each of the links is an elongated rigid member formed of stainless steel or some other suitable biocompatible material, e.g., tantalum, plastic. Each link has a pair of ends 32A and 32B and is joined to an associated link via a pivotable joint 34. Each joint 34 is made up of one end 32A of one link and the other end 32B of the immediately adjacent link. The link ends 32A and 32B are connected by any suitable means, e.g., a deformable member, a pin, etc., to enable the links to pivot outward with respect to each other so that the angle therebetween increases, yet which precludes the links from pivoting backward toward each other. When so arranged the links form a zig-zag pattern. (Rhodes, column 6, lines 32-46) (emphasis added)

Such description is consistent with the detailed stent drawings of Rhodes, i.e. Figures 8 and 9, which are reproduced below for convenience of the examiner..



The straight elongate strut members of Rhodes do not read on the stents of the invention as set forth in the independent claims because the straight and elongated strut members of Rhodes are not helically wound undulating wires.

Thus, Rhodes fails to disclose, *inter alia*, a stent scaffold consisting essentially of helically wound undulating wires having alternating peaks and valleys to define turns thereat, as set forth in independent claim 1 and a stent scaffold having V-shaped or quadrilateral-shaped

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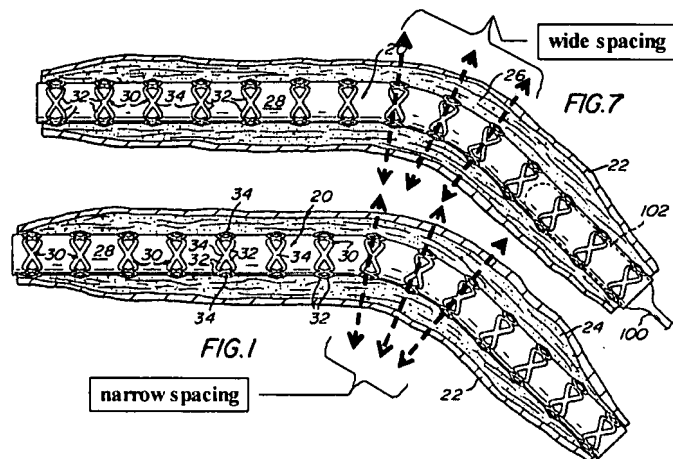
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cells consisting essentially of helically wound undulating wires having alternating peaks and valleys to define turns thereat as set forth in independent claim 23.

Assuming *arguendo* that one could somehow read the strut members of Rhodes to be undulating wires, Rhodes still fails to disclose each and every limitation as set forth in the independent claims. Independent claim 1 requires that the wires and their turns are distributed substantially equally and uniformly displaced along the length of the prosthesis, including being distributed substantially equally and uniformly displaced along the length of the segment of curvature. Independent claim 23 requires that the wires and their turns are distributed substantially equally and uniformly displaced along the length of the prosthesis, including being distributed substantially equally and uniformly displaced along the length of the segment of curvature.

In Figures 1 and 7, Rhodes clearly shows that its stent members are not evenly and constantly distributed through its area of curvature. The stents are clearly relatively closer to each other at the lower portion of the bend in Figures 1 and 7, and are clearly relatively spaced further apart at the upper portion of the bend in Figures 1 and 7. This is in direct contrast to the claimed limitations of the independent claims of the subject application. For the convenience of the examiner Figures 1 and 7 are reproduced below with vectors added showing the discontinuity of the stent elements of Rhodes through areas of curvature of its stent, as follows:



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Moreover, with respect to independent claim 23, applicants respectfully submit that the phrase “wherein the wires have an increased pitch at the outside segment and have a reduced pitch at the inside segment when disposed on a straight mandrel” is not a statement of mere intended use, but is rather a structural limitation. Claim 23 clearly states, *inter alia*, that “the wires and their turns are distributed substantially equally and uniformly displaced along the length of the prosthesis, including being distributed substantially equally and uniformly displaced along the length of the segment of curvature.” Claim 23 further states that the segment of curvature comprises “an inside [segment] of the curvature and an outside [segment] of the curvature.” Thus, claim 23 defines the positioning of the stent elements in an area of curvature. When the stent is a longitudinally straight orientation, i.e., disposed on a straight mandrel, the above substantially equal orientation of the undulating wires and their turns are not maintained, but are shifted as recited. Thus, claim 23 reads that in one stent orientation, the stent elements have a first structural orientation and in a second orientation the stent elements have a second structural orientation. Applicants respectfully submit that such limitations in claim 23 are not mere statements of intended use, but are structural limitations.

The action relies on two court cases dealing with intended use of devices. In one case applicant had claimed a machine and had argued that a prior art machine performed a different task. *In re Casey*, 152 USPQ 235, 238 (CCPA 1967). The court ruled that the “manner or method in which such a machine is to be utilized is not germane to the issue of patentability of the machine itself”. *Id.* In the second case, applicant had argued that a claimed hair curling device would operate differently and would further operate with a different hair curling composition than a prior art device. *In re Otto, Otto and Briton*, 136 USPQ 458, 459 (CCPA 1967). Again the court ruled that the structure of the device is the issue and not its intended use. *Id.* at 460. In contrast, the limitations of claim 23 set forth two different structural limitations, one limitation when the stent is curved and another limitation when the stent is not curved, i.e., straight. Unlike the cases cited by the Examiner where no structural differences of devices were in themselves being argued, structural limitations are recited in independent claim 23 as opposed to mere statements of intended use, as present in the above court cases.

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It should be noted that the device of Rhodes is in direct contrast to the claimed structural limitations of claim 23. The stent elements of Rhodes are uniformly longitudinally disposed when the stent is in a straight condition, but are longitudinally skewed when the stent is in its curved orientation. For the reasons set forth above, the examiner may not properly ignore such structural differences because the limitations of claim 23 are structural limitations and not statements of mere intended use.

Thus, Rhodes fails to disclose each and every limitation of the endoluminal prosthesis as set forth in independent claims 1 and 23. Therefore reconsideration and withdrawal of the rejections of claims 1-9, 13, 15, 17-24, 27, 29, 31, 33-37 and 42-45 under 35 U.S.C. §102(b) are respectfully requested.

Section 103 Rejections

Claims 12-14 and 28 and 30 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Rhodes in view of U.S. Patent No. 4,994,071 to MacGregor (hereinafter "MacGregor"). Applicant respectfully traverses.

MacGregor is cited by the Examiner for its teachings regarding different stent materials. MacGregor, however, fails to cure the deficiencies of Rhodes. MacGregor describes a bifurcated stent 10 having a main tubular body or lattice 16 and two tubular legs or lattices 20, 23. (MacGregor, column 3, lines 54-68, Fig. 1). The lattices 16, 20, and 22 have a series of loops 12, 12'', 12', respectively, which are depicted as undulating looped wires. (*Id.*) A longitudinally extending wire 24 interconnects loops 12 and 12' and further interconnects lattices 10 and 22. (MacGregor, column 4, lines 1-4). A second longitudinally extending wire 26 similarly interconnects loops 12 and 12'' and lattices 10 and 20. (MacGregor, column 4, lines 5-10).

The stent portion 16, 20 and 22 are depicted in Figs. 1 and 1A as being substantially straight members, i.e. having no segments of curvature along any longitudinal axis. The wires 24, 26 are substantially straight in the longitudinal direction, i.e., not undulating wires, except for a bend at the point of bifurcation. (MacGregor, column 4, lines 10-14; Fig. 1). Thus, as

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depicted in Fig. 1, the wires 24, 26 are not undulating wires, and these non-undulating wires do not have turns that are distributed substantially equal along the length of the stent because the wires have only one bend at the point of bifurcation.

Further, MacGregor fails to describe that any of the loops 12, 12', 12", or undulating wires, may extend through the area of bifurcation, i.e., curvature. In other words, there is a discontinuity of the stent configuration at the area of bifurcation. (see e.g., MacGregor, Fig. 1A). The general depictions of Figs. 2A-3D, which schematically show the placement of the MacGregor stent within body vessels 50, 50a, 50b, depict portions of the stent being curved, but fail further detail the area of bifurcation, i.e., fails to show any wires and their turns being distributed substantially equally along the length of the device, including being distributed substantially equally and uniformly along the portion of curvature.

Thus, MacGregor fails to cure the deficiencies of Rhodes because the wires 24, 26 of MacGregor only have one turn at the point of bifurcation and the turn is not therefore equally distributed along the length of the stent. Further, the stent coils 12, 12', 12'' of MacGregor are not equally distributed over the length of the stent due to discontinuity at the point of bifurcation.

Accordingly MacGregor fails to cure the deficiencies of Rhodes. Thus, Rhodes and MacGregor, individually or in combination, fail to teach or suggest the present invention. Therefore, reconsideration and withdrawal of the rejections of claims 12-14 and 28 and 30 under 35 U.S.C. §103(a) are respectfully requested.

Claims 11 and 27 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Rhodes in view of U.S. Patent No. 4,553,545 to Maass et al (hereinafter "Maass"). Applicant respectfully traverses.

Maass is cited by the Examiner for its teaching of shape memory alloy stent materials. Maass, however, describes a helically shaped coil spring or stent. (Maass, column 1, lines 9-12; Figs. 1-6). Thus, Maass, fails to teach or suggest, *inter alia*, a stent scaffold having V-shaped or quadrilateral-shaped cells, where the stent scaffold consisting essentially of helically

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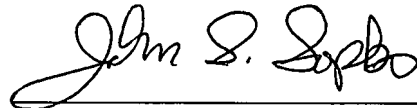
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wound undulating wires having alternating peaks and valleys to define turns thereat. Further, Maass fails to teach or suggest such a stent scaffold as having the wires and their turns being distributed substantially equally and uniformly displaced along the length of the prosthesis, including being distributed substantially equally and uniformly displaced along the length of the segment of curvature.

Thus, Rhodes and Maass, individually or in combination, fail to teach or suggest the present invention. Therefore, reconsideration and withdrawal of the rejections of claims 11 and 27 under 35 U.S.C. §103(a) are respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John S. Sopko". The signature is fluid and cursive, with a long horizontal stroke extending from the end of the name.

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